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I must begin my general comments on the proposed changes in the regulation of treatment for opioid addiction by saying that I have found, as a patient advocate in Tennessee, that the Federal Government has been the best source of current information and treatment guidelines for the modality. The interaction between federal agencies and professional associations has promoted the development of "best practice" standards that, if uniformly applied, would resolve many of the issues contributing to the treatment gap for opioid addiction, and the less-than-effective use of this modality. The Center for Substance Abuse Treatment has contributed greatly to the dissemination of those standards, especially concerning opioid agonist therapy. I generally believe that the move to accreditation will benefit patients and communities.

Regulatory authority of States

Patients currently suffer greatly from ignorance of the disease of addiction, its treatment, and specifically, agonist therapy, both on the part of the community, and especially the medical community including a significant number of treatment providers. TIP # 1 (*State Methadone Treatment Guidelines*) was one of the first publications I encountered when I began volunteering as a patient advocate. I was amazed to find that the providers in Tennessee were either not familiar with it, or if they were, had not READ it, and only seemed interested because I pressed them about the information it contained! Inadequate dosing, restrictive and punitive clinical schedules, and ineffective counseling attitudes are primary concerns.

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The situation in Tennessee is critical in that patients have little choice in treatment providers, and often travel very long distances to get treatment, which is expensive and without supportive public funding. Medicaid has covered MMT at a few Community Mental Health Centers here, but currently there are no such programs. The Medicaid 1115 Waiver (TennCare) has caused continual difficulty in access for enrollees in that the State denied it was a covered service until recently, and now challenges every request on the basis of the medical necessity of maintenance treatment. Privately operated treatment providers (the only current providers) charge $10-$12 per day, which is prohibitive for patients with fixed or limited income. Although cost-effective when compared to active addiction, or other treatment modalities (for which relapse rates must be considered in total cost), for "cash-only, pay-as-you-go treatment," the drop-out rate due to financial difficulty is a significant problem.

The current federal regulations are minimum standards and States can regulate any aspect of treatment more severely if they wish. There must be some way to ensure that any additional state regulation does not diminish the effectiveness of opioid agonist treatment. Dosing caps, approval of doses over X amount by the State Authority (who might NOT be a doctor), limits on take-home amounts, required minimum group or individual counseling time for all patients, etc. are commonplace practices instituted by state regulation that have a detrimental effect on many patients. It is hoped that oversight by SAMHSA will facilitate an improved environment in states such that these kinds of practices will be eliminated. Although technical assistance is currently available to state agencies through CSAT, only state agencies are able to initiate a request for such assistance and oftentimes do not perceive a problem with their attitude or practice in regulating OTPs. If accreditation will address the need for patient, advocate, medical and public input into the practices of OTPs or the regulation of them by state agencies, this problem might be solvable.

"... the Secretary will not require that the program first obtain approval from a relevant State authority."

How can programs expect to open if approval from state authorities is not received first? Siting a program in Tennessee is very costly, and a long process. A Certificate of Need is required, which means that a program must already have a leased building and acquired a Medical and Program Director. The CoN process takes approximately 3 months, during which the empty building must be leased and staff paid. If the CoN is granted, the actual licensing process takes additional time, and additional fees. This is a major and risky investment for providers. Because all licensing and certification processes are site-specific, initial state approval will remain a de facto requirement.

Accreditation Impact Study

How responsive to the outcome studies will the proposed regulations be? How difficult and time consuming will it be to change what appears to be ineffective or burdensome in the proposal? This modality and its beneficiaries have suffered from regulatory neglect for so long that any additional delay due to regulatory processes should be minimized.

§8.3(a) Activity level of accrediting bodies.

I think that allowing state government entities to become accreditation bodies is a favorable action. But many State governments have traditionally been resistant to allowing methadone programs to operate, or to operate effectively (allowing as many as are indicated by the levels of opioid abuse in the state, creating restrictive regulations concerning clinical practice which limit the effectiveness of the modality, etc.). The issue of state control over programs is problematic. The issue is generally a lack of adequate education about opioid agonist treatment and its most effective use.

According to the Uniform Facilities Data Set, 1997, only 2 states could qualify under the Secretary's proposal as accreditation bodies. If this standard for accrediting bodies were lowered so that more states could qualify, some of these states may be encouraged to increase the number of programs available, and retain a comfortable level of control, but in an improved environment with patient-centered, research-based clinical standards of care.

The states with more than 9 licensed programs (which may include hospitals which do not operate "programs" per se, but can medicate with methadone for a limited amount of time) are listed below. Some states that may be problematic in their attitudes to OTPs because of fear of the modality might be more inclined to view it positively if they become more knowledgeable and feel that they can maintain an element of control. Because of this, and because the proposal intends to expand access and improve quality, it may be more effective to allow state accrediting bodies to be certified who would oversee fewer programs than proposed. If the number under the state's oversight were reduced to at least 10, seventeen states might be eligible. With accreditation covering 3 years, this might be problematic in maintaining expertise on the part of reviewers, but it might also encourage states to confidently expand the number of treatment programs available. State agencies have a wide variety of duties, and the additional task of accrediting OTPs would have to be such that it could be incorporated easily into existing structures/duties and the need to survey a reduced number of facilities per year may make that manageable.

Qualified by number of programs operating in the state:

NY	175	CA	112				

States with less than 50 but more than 20

MD	37	TX	37	IL	36	PA	35
MI	30	MA	29	CT	28	NJ	21

States with between 10 and 20 programs

AZ	20	FL	20		
VA	14	GA	13		
AL	11	OH	11	WA	11

All of these states have populations over 3 million, which, based on IOM and other estimates of heroin addiction rates, would indicate that at least 12,000 people in each state are currently addicted and would benefit from opioid agonist treatment. This estimate does not include those who are addicted to pharmaceutical opioids. The treatment gap is huge, and resistance to expansion on the part of state governments is a crucial factor maintaining that gap in many states.

Procedures for Suspension/Revocation of Certification and Accreditation Body Approval.

The review process should be administered by SAMHSA with DEA participation. Either agency should be able to initiate the process, but ultimately, SAMHSA should decide whether an accreditation body could be brought to standards or should have certification revoked or denied.

Federal Opioid Treatment Standards, Criteria for Admission to Treatment.

A waiting period of 2 to 3 days is more reasonable at this time. Many states have restrictions on admission to maintenance therapy (more severe than the federal guidelines) and patients use detoxification episodes to prolong their treatment stay. In addition, infectious disease is not the only risk for out-of-treatment addicts. Any crime involved in procurement of opioids also creates a significant risk.

Office-Based Treatment.

The proposal appears to be sufficiently flexible to allow OBT under Subpart B, §8.11(h) [exemptions] and (i) [medication units]. OBT exemptions could be standardized under this paragraph according to the recommendations of the panel currently reviewing OBOT until such time as they have been sufficiently studied to warrant separate rules. Delaying the current (long awaited) proposal to include separate rules seems unnecessary considering the flexibility that SAMHSA indicates it intends to maintain in the regulation of OTPs.

Medications Dispensed for Unsupervised Use (*Take-homes*)

Option 2 is the most reasonable, with one adjustment. In order to establish a smoother transition to monthly visits, I would suggest that the period between the third month of treatment and the end of the first year allow for weekly visits (perhaps in the fifth or sixth month) rather than continuing with twice weekly visits. Since the amount of take-home medication allowed should be based on the individual patient's progress in treatment, adjusting these guidelines may reduce the need to request exemptions for patients who have retained stable functioning despite their addiction and for whom weekly visits are

the least disruptive because of employment, school or other responsibilities, or travel. Some providers have indicated that the transition also include a period of twice monthly visits before allowing a patient to come monthly although this is easily accomplished after the first year by clinical policy.

Risk of diversion is, for many patients on fixed incomes or with low incomes, directly related to the cost of treatment (reason to sell) and the difficulty of accessing treatment (available buyers). These may be the most important factors, considering the IOM discussion of diversion and this has been the case in my personal experience working with patients in Tennessee.

Subsidized treatment is not uniformly available in the states. Universal coverage of opioid agonist treatment by both public and private insurance would be the most significant factor in reducing the risk of this most common reason for diversion.

Additional comment on pharmacy standards:

Some providers require re-use of bottles, placing responsibility on patients for sanitation. If this is the standard for pharmacies outside of the clinic system (although I have never had a refill of liquid medication placed in anything but a new bottle), then this might appear more acceptable. This re-use practice seems to violate the most basic sanitation standards for medication and should be addresses in the federal treatment standards.

I have not noticed an appreciable difference in total treatment cost between providers who use new bottles and those who don't.